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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,469	06/05/2001	Oddone Schiavon	2548-13	4731

7590 04/23/2003

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EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,469	SCHIAVON ET AL.	
	Examin r	Art Unit	
	Sandra Wegert	1647	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *11 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 7* is/are rejected.

7)☒ Claim(s) *2-8, 9, 10, 12* is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Preliminary Amendment, submitted 5 June 2001, has been entered into the record as Paper No. 5. Claims 1 and 6-8 were amended. Claims 9-13 were added. The Information Disclosure Statement, filed 5 June 2001, has been entered into the record as Paper No. 5. Applicant's election of the following Species is acknowledged: *Interferon*, *Met-Nle*, and *PEG*. Applicant's election with traverse of Species *Interferon*, *Met-Nle*, and *PEG* is noted. The traversal is on the ground that the Inventions are linked under PCT rule 13.1 because there is no evidence that "FE is advantageously the specific linkages recited in [generic claims]". Applicant's arguments are not persuasive, however, since the species in question were properly restricted as independent and distinct products having characteristic differences in structure and function and having different uses as noted in Paper 9 (10/1/02). More importantly, there is art that can be applied to the first named invention before Restriction/Election (Veronese, et al, 1991, Patent WO 91/01758). And, since a complete search of the art includes a search of the art that renders an invention obvious as well as anticipatory, the additional searches required for examination of all recited Species would be extensive, thus presenting an undue burden for the examiner. Claims 11 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as reciting only non-elected species, there being no allowable generic or linking claim.

Claims 1-10 and 12 are under examination in the instant application.

Informalities

Specification

The disclosure is objected to because of the following informalities:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is *suggested*: "POLYETHYLENE-INTERFERON CONJUGATE"

Appropriate correction is required

Claim Rejections/Objections

Claim Objections -

Claims 1 and 6-8 are objected to for reciting non-elected subject matter.

Claim Rejections - 35 USC § 112, second paragraph, indefiniteness.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 7 are rendered indefinite because Claim 7 provides for the use of Gln-Gly or Asp-Pro, but, since the claims do not set forth any steps involved in the method/process whereby the peptides are cleaved, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Note: The closest prior art is: Veronese, et al (1991, Patent WO 91/01758) in view of Sartore, et al (1991, Appl. Biochem. Biotechnol., 27(1): 55-63). These references taken together do not read on the instant Claims because they do not recite the dipeptide linker (eg., Met-Nle, Met-Gly, Gln-Gly or Asp-Pro) recited in the claims.

Conclusion: Claims 1 and 7 are rejected for the reasons put forth above. Claims 6-8 are objected to for the reasons listed above. Claims 2-5, 9, 10, and 12 are objected to for depending from a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

4/15/03

Gary L. Kunz

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